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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,708

06/02/2005

Yasunori Shiraki

10921.323USWO

6556

52835

7590

12/23/2008

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

DINH, BACH T

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,708	Applicant(s) SHIRAKI ET AL.	
	Examiner BACH T. DINH	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) 8, 15, 16 and 22-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/02/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the initial Office Action based on the 10/537,708 application filed on 06/02/2005.
2. Claims 1-23 are currently pending and have been fully considered.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

4. Claim 8 is objected to because of the following informalities: at line 8, "electrode" is believed to be a misspelling of "electrodes".
5. Claim 15 is objected to because of the following informalities: at line 5, "plan" is believed to be a typographical error of "plane".
6. Claim 16 is objected to because of the following informalities: at line 2, "plan" is believed to be a typographical error of "plane".
7. Claim 22 is objected to because of the following informalities: at line 3, "expect" is believed to be a typographical error of "except".
8. Claim 23 is objected to because of the following informalities: at line 3, "plan" is believed to be a typographical error of "plane".
9. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-12 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Winarta et al. (US 6,287,451).

Independent claim 1 recites "an analytical tool to be mounted to an analytical apparatus" and subsequent dependent claims recite "the analytical tool". Therefore, patentability of the analytical tool is determined based on the structure of the analytical tool itself and not the way in which the analytical tool is mounted to the analytical apparatus or the structures of the analytical apparatus or the effects on the analytical tool when the analytical tool is mounted to the analytical apparatus.

Addressing claim 1, Winarta discloses an analytical tool (sensor 10, figure 2) including a plurality of electrodes (electrodes 22, 24, 26 and conductive layer formed by scoring line 28, figure 2);

Wherein, at least one of the electrodes serves as a disturbing noise countermeasure electrode to which disturbing noise is more likely to come in comparison with the other electrodes than the at least one of the electrodes (6:25-30, electrode area W1 is used as the interference-correcting electrode, wherein the current response from W1 is compared with current response of W2; furthermore, 7:54-56, scoring line is used

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to form individual conduits from the conductive layer 21 on the surface of base layer 20; therefore, the layer formed by scoring line 28 is conductive and is used to reduce potential static problems that give rise to noisy signal; 7:63-8:1; therefore, either electrode W1 or the conductive layer formed by scoring line 28 is the claimed disturbing-noise countermeasure electrode).

Addressing claim 2, Winarta discloses the sensor 10 includes a first electrode (electrode R) and a second electrode (electrode W1) for applying voltage to a target portion in cooperation with the first electrode (11:62-66, potential is applied between the working W1 and the reference electrode R with the reagent layer covering the working and reference electrodes being the claimed target portion). The electrode W1 serves as the interference-correcting electrode as addressed above.

Addressing claims 3-4, the subject matter of current claims are not given weight because they are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself.

Addressing claim 5, Winarta discloses the sensor includes a first electrode (electrode R), a second electrode (electrode W1) for applying voltage to a target portion in cooperation

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with the first electrode (11:62-66, potential is applied between the working W1 and the reference electrode R with the reagent layer covering the working and reference electrodes being the claimed target portion), and a third electrode (conductive layer formed by scoring line 28) which is not involved in the voltage application to the target portion, and

The third electrode serves as the disturbing-noise countermeasure electrode (7:63-8:1).

Addressing claims 6-7, the subject matter of current claims are not given weight because they are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. See the discussion of claims 3-4 above.

Addressing claim 8, Winarta discloses the sensor includes a first electrode (electrode R), a second electrode (electrode W1) for applying voltage to a target portion in cooperation with the first electrode (11:62-66, potential is applied between the working W1 and the reference electrode R with the reagent layer covering the working and reference electrodes being the claimed target portion), and a third electrode (conductive layer formed by scoring line 28) which is not involved in the voltage application to the target portion, and

The second and third electrodes serve as the disturbing-noise countermeasure electrodes (6:25-30, electrode W1 is the interference correcting electrode; 7:63-8:1, conductive layer formed by scoring line 28 reduces noisy signal from static potential).

Addressing claims 9-10, the subject matter of current claims are not given weight because they are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. See the discussion of claims 3-4 above.

Addressing claim 11, Winarta discloses a flow path for moving a sample (fluid channel 112, figure 1) and an air vent for discharging air from the flow path (air vent 52, figure 1).

Addressing claim 12, Winarta discloses the electrode W1 includes an input portion to which disturbing noise coming through the air vent is inputted (in figure 2, reagent layer on electrode area W1 is in communication with the air vent 52 via the channel 42; therefore, disturbing noise coming through the air vent 52 would be inputted to the reagent layer of electrode area W1).

Addressing claim 17, Winarta discloses the disturbing-noise countermeasure electrode (conductive layer formed by scoring line 28) surrounds the electrode areas W1, R and W2 of conduits 22, 24 and 26.

Addressing claim 18, Winarta discloses a substrate (substrate 20) on which the plurality of electrodes are formed (figure 2), wherein the disturbing-noise countermeasure

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electrode is formed along a peripheral of the substrate (conductive layer formed by scoring line 28 is around the periphery of the substrate).

Addressing claim 19, the subject matter of current claim is not given weight for it is directed to the mounting of the analytical tool to the analytical apparatus. See the discussion of claims 3-4 above.

Addressing claim 20, in figure 2, portion of conduit 22 of electrode W1 and portion of conductive layer formed by scoring line 28 are located at a position closer to the right edge or the insertion edge of the sensor 10 than the other electrodes.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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14. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. (US 6,287,451).

Addressing claims 13-14, Winarta fails to disclose the input portion (reagent layer of electrode W1) is provided directly below the air vent and is partially exposed via the air vent.

Winarta discloses the arrangement of the electrodes can be R-W2-W1 (8:58-61); wherein, electrode area W1 is provided at cut out 36.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the sensor of Winarta with the arrangement R-W2-W1 for the electrode areas because the aforementioned arrangement of the electrode areas is listed in a finite number of electrode areas arrangements (Winarta, 8:58-61). Therefore, one would have expected success when modifying the sensor of Winarta with the electrode areas arrangement R-W2-W1. In the R-W2-W1 arrangement, electrode area W1 is formed from the cut out 36 of layer 30, which is provided directly below the air vent 52 and partially covered by insulating spacer 40 (7:44-46). The channel 42 of insulating layer 40 is the claimed opening for partially exposing the electrode area W1 to the air vent 52 (9:5-13).

Addressing claims 15-16, Winarta discloses a substrate (substrate 20) on which the plurality of electrodes are formed (figure 2), and a cover (layer 50) which is bonded to the substrate and in which the air vent 52 is formed (figure 2).

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When the electrode areas are placed in the arrangement R-W2-W1, as addressed in the rejection of claims 13-14 above, and the air vent 52 exposes a portion of the cut out 42 (9:5-13), the reagent layer of electrode area W1 or claimed input portion includes a part located at the periphery of the air vent. Furthermore, the input portion surrounds the air vent for it is provided at the periphery of the air vent.

15. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. (US 6,287,451) in view of Rappin et al. (US 6,572,745).

Addressing claim 21, Winarta fails to disclose the sensor comprising a pinch portion.

Rappin discloses a biosensor; wherein, the side of the biosensor 310 has contour portions or claimed pinch portions located at the sides of the body (figure 13, 11:45-48).

Winarta and Rappin are analogous arts for they disclose biosensors. At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor of Winarta with the contour portions on the biosensor body like that of Rappin because the contour portions allows easy insertion of the biosensor to the meter (Rappin, 11:45-48).

Addressing claim 22, Winarta fails to disclose the conductive layer formed by scoring line 28 is covered by an insulating film except for an exposed portion adjacent to the pinch portion.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the insulating film of the biosensor of Winarta to expose a portion of

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the conductive layer formed by scoring line 28 at the pinch portion because exposing the portion of the conductive layer allow more effective discharge of the potential static that would give rise to noisy signal (Winarta, 7:63-8:1).

Addressing claim 23, in figure 13, Rappin discloses the pinch portion comprises a recess which is inwardly sunk in plan view of the biosensor 310.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zivitz (US 6,858,433) discloses a biosensor with a noise cancellation loop 32 surrounds the reaction zone 22 (figure 3).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BACH T. DINH whose telephone number is (571)270-5118. The examiner can normally be reached on Monday-Friday EST 7:00 A.M-3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795

BD
12/16/2008